

REMARKS

In the Office Action, Paper No. 5, all pending claims 1-69 were rejected. In response thereto, claims 9, 11, 20, 61, 62, and 65 have been amended herein, claims 10, 12-13, 29-60, 63-64, and 67-68 have been cancelled, and new claims 71-73 have been added. Support for new claim 71 can be found in the Specification at paragraphs [0039] and [0051]. Support for new claims 72 and 73 can be found in the Specification at paragraphs [0040], [0060] and [0064]. As a result of this amendment, claims 1-9, 11, 14-28, 61-62, 65-66 and 69-73 remain pending for the Examiner's consideration. In addition, the Specification was amended to correct obvious typographical errors. None of the amendments set forth herein constitute the addition of new matter. Reconsideration of the application as amended is respectfully requested.

It is noted that claim 69 was not included in any of the objections or rejections in this Office Action, and therefore should be allowable. Clarification of the status of claim 69 is respectfully requested.

A. Objection to Specification Addressed

The disclosure is objected to because of the typographical errors on page 5, line 21 and on page 14, line 21. The Specification has been amended herein to replace the phrase "red currents" with "red currants" to correct this typographical error.

B. Claim Objections Addressed

Claims 20 and 44 are objected to because of a typographical error. Claim 20 has been amended herein to replace the phrase "red currents" with "red currants," and claim 44 has been cancelled, thereby addressing this objection.

C. Rejections under 35 U.S.C. § 112, First Paragraph, Addressed

Claims 1, 14, 24, 36, 39, 48, 54, and 58 are rejected under 35 U.S.C. § 112, first paragraph, for various reasons. Claims 36, 39, 48, 54 and 58 have been cancelled herein. With respect to claims 1, 14 and 24, it is asserted that these claims are fully enabled as discussed below.

1. The Office Action states that "the specification, while being enabling for a plant material such as blueberries, bilberries, blackberries, strawberries, red-currants, black-currants, cranberries, and etc. does not reasonably provide enablement for all the well-known plants in the world." This rejection is respectfully traversed.

The first paragraph of Section 112 requires that a patent application be written so as to "enable any person skilled in the art which it pertains . . . to make and use the same." A Specification is presumed to be enabling absent "a reasonable doubt to the objective truth of the statements contained therein." *In re Marzocchi*, 169 USPQ 367, 369 (CCPA 1971). Additionally, a Specification "may be enabling even though some experimentation is necessary." *United States v. Teletronics, Inc.*, 857 F.2d 778, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988), so long as the amount of experimentation required is not "undue experimentation." *In re Wands*, 858, F. 2d 731, 8 USPQ2d 1300, 1303 (Fed. Cir. 1988). "As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied." *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (emphasis added).

It is asserted that all of the novel elements of claims 1, 14 and 24 are fully enabled by the Specification. In general, claim 1 is directed to a method of preparing a composition enriched for anthocyanins. The method involves preparing an extract from a plant that contains anthocyanins, filtering the extract, and isolating the anthocyanins from the extract using a brominated polystyrene resin. The surprising and unexpected discovery of this invention (and the crux of claim 1) is that since the binding properties of brominated polystyrene resin were known to bind anthocyanins tighter than conventional polystyrene resins, it was not expected that a brominated polystyrene resin would be suitable for the purification of anthocyanins. However, it was surprisingly and unexpectedly discovered that the brominated polystyrene resin binds anthocyanins less tightly than non-brominated polystyrene resins, but still allows for the separation of anthocyanins from undesired extraneous impurities that are more polar than the anthocyanins (see paragraph [0036]). Thus, the critical step of this method is the isolation of the anthocyanins using the brominated polystyrene resin, and this step has been fully described and enabled in the specification. The other steps of this method, e.g., the step of providing an extract of a plant containing anthocyanins, the filtering step, the washing step, the eluting step, etc. use techniques that are well known in the art and therefore do not need detailed descriptions in order to provide sufficient enablement. Further, as will be discussed below, the plant materials used in the method of claims 1, 14 and 24 (i.e., plants containing anthocyanins) have been adequately described and enabled in the specification.

First, the Examiner's remark that claims 1, 14 and 24 are not enabled because the Specification does not reasonably provide enablement for all the well-known plants in the

world indicates that the Examiner has misunderstood the invention. The present invention is not trying to claim "all the plants in the world." Rather, claim 1 recites a method of preparing a composition enriched for anthocyanins, wherein one of the method steps comprises providing a crude extract of a plant material that contains anthocyanins. That is, the method requires that the extract be prepared from a plant material that contains anthocyanins, as opposed to "any plant in the world" as alleged by the Examiner. As stated in paragraph [0002] of the Specification, "[a]nthocyanins are naturally occurring compounds that are responsible for the red, purple, and blue colors of many fruits, vegetables, cereal grains, and flowers. For example, the colors of berry fruits, such as blueberries, bilberries, strawberries, raspberries, boysenberries, marionberries, cranberries, are due to many different anthocyanins." The Examiner's attention is further drawn to paragraph [0023] of the specification which states "the term "extract" refers to a substance derived from a plant source that naturally contains anthocyanins, including extracts prepared from the whole plant or from various parts of the plant, such as the fruit, leaves, stems, roots, etc. . . . Examples of plants and fruits that may be used in the preparation of the purified extracts of this invention include any plant, including fruits and vegetables, that contains anthocyanins, including blueberries, bilberries, blackberries, strawberries, red currants, black currants, cranberries, cherries, raspberries, grapes, currants, elderberries, hibiscus flowers, bell peppers, red cabbage, purple corn, and violet sweet potatoes. Most colored fruits and vegetables are known to contain anthocyanins" (emphasis added).

It is asserted that the specification provides sufficient guidance to allow one of skill in the art to practice the present invention without undue experimentation. Thus, the invention should not be limited to the specific plants named in the list of examples, but rather the inventors should be entitled to claim their unique process for preparing an anthocyanin-enriched composition using any plant that contains anthocyanins. Further, the Courts have determined that Applicants are not required to provide examples of every embodiment encompassed by the claims. *In re Angstadt*, 537 F.2d 498, 190 USPQ 214 (CCPA 1976). Assessing an analogous rejection in *In re Angstadt and Griffen, supra*, the court stated:

To require such a complete disclosure would apparently necessitate a patent application with "thousands" of examples or the disclosure of "thousands" of catalysts along with the information as to whether each exhibits catalytic behavior resulting in the production of hydroperoxides. More importantly, such a requirement would force an inventor seeking adequate patent protection to carry out a prohibitive number of actual experiments. This would tend to discourage inventors from filing patent applications in an unpredictable area

since the patent claims would have to be limited to those embodiments which are expressly disclosed. A potential infringer could readily avoid "literal" infringement of such claims by merely finding another analogous catalyst complex . . .

Thus, if the Examiner cannot establish that any plant that contains anthocyanins could not be used in the method of this invention, then he must concede that the claims as pending are enabled and that the 35 U.S.C. § 112, first paragraph, rejection is improper and should be withdrawn.

2. The Office Action states that the Specification, "while being enabling for a filter aid, such as diatomaceous earth or cellulose, does not reasonably provide enablement for all the filter aids known in the world". This rejection is respectfully traversed. The above-discussion regarding the requirements for enablement pertains to this rejection as well. Methods of filtering extracts are well known to those skilled in the art. Further, the type of filtering material used in the filtering step of claims 1, 14 and 24 is not critical to the method. Rather, all that is required is that the crude extract be filtered (to remove solids that may have precipitated from the crude extract) prior to contacting the crude extract with the brominated polystyrene resin. Any filtration method known in the art may be employed in filtration step of claims 1, 14 and 24 (see paragraph [0046]). It is therefore asserted that this invention should not be limited to the specific filtering methods disclosed in the specification as non-limiting examples, but rather the inventors should be entitled to claim their unique process for preparing an anthocyanin-enriched composition using any filtering method. As stated above, Applicants are not required to provide examples of every embodiment encompassed by the claims. *In re Angstadt, supra*. Accordingly, it is asserted that claims 1, 14, and 24 are fully enabled with respect to the filtering step, and it is respectfully requested that this enablement rejection be withdrawn.

3. The Office Action states that the Specification, "while being enabling for an excipient, such as preservatives, carriers, . . . flavoring agents, etc., does not reasonably provide enablement for all the excipients known in the world". This rejection is respectfully traversed. Claim 24 further limits the invention of claim 1 by reciting that the enriched composition is combined with an excipient. The use of excipients for formulation compounds or drugs into pills, tablets, etc. is so well known in the art that it is unnecessary to list all of the excipients which could be used in the method of this invention. Further, as

stated above, Applicants are not required to provide examples of every embodiment encompassed by the claims. *In re Angstadt, supra*. Therefore, although the Specification does not provide examples for every possible embodiment encompassed by claim 24 (which would be prohibitive), the specification does provide enough guidance so that a worker can make and use the invention without undue experimentation. As such, it is asserted that the scope of claim 24 is fully enabled by the specification, and it is respectfully requested that this enablement rejection be withdrawn.

4. The Office Action states that the specification, while being enabling for a reversed phase resin, such as polymethacrylate, . . . etc., does not reasonably provide enablement for all the reversed phase resins known in the world. The claims that contain the rejected term (claim 39 and its dependants) have been cancelled herein, thereby obviating this rejection.

D. Rejections under 35 U.S.C. § 112, Second Paragraph, Addressed

Claims 9, 25, 29, 33, 49, 55 and 59 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for various reasons discussed below.

1. The Office Action states that the phrase "an extraction solvent" is vague and indefinite as to what "extraction solvent" can be used in the process. This rejection is respectfully traversed. Claims 29, 33, 49, 55 and 59 have been cancelled herein. With respect to claim 9, which contains the rejected term, it is asserted that the term "extraction solvent" is clear and definite when viewed in light of the specification. However, in an effort to expedite prosecution, claim 9 has been amended herein to incorporate the language of claim 10 to recite that the extraction solvent is "an aqueous solution having between about 0-95% ethanol and between about 0.5-3% acid or an aqueous solution having between about 0-100% methanol and between about 0.5-3% acid". Accordingly, claim 9 is clear and definite, and withdrawal of this rejection is respectfully requested.

2. The Office Action states that the group of words "preservatives, carriers, buffering agents, . . . and flavoring agents," is indefinite since each of them is unspecified in the claims and the specification. This rejection is respectfully traversed. Excipients such as preservatives, carriers, buffering agents, etc. are so well known in the art that it is unnecessary for the applicant to provide definitions of such terms. However, the

specification does provide clear definitions at paragraph [0055], which state that "excipients include preservatives, carriers, and buffering, thickening, suspending, stabilizing, wetting, emulsifying, coloring and flavoring agents, and in particular carboxy vinyl polymers, propylene glycol, ethyl alcohol, water, cetyl alcohol, saturated vegetable triglycerides, fatty acid esters or propylene glycol, triethanolamine, glycerol, starch, sorbitol, carboxymethyl cellulose, lauryl sulphate, dicalcium phosphate, lecithin, etc." Accordingly, it is asserted that Specification provides a suitable number of examples of preservatives, carriers, buffering agents, etc. that the meaning of this phrase in claim 25 is clear and definite. Withdrawal of this Section 112, second paragraph, rejection is respectfully requested.

3. The Office Action states that the phrase "plant sterols, flavonoid glycosides, fatty acids, triglycerides, and other impurities" is vague and indefinites. This phrase was contained in claim 29, which has been cancelled herein, thereby obviating this rejection.

E. Rejections under 35 U.S.C. § 102(b) addressed

1. Rejection of claims 61-64 over Levy et al.

Claims 61-64 are rejected under 35 U.S.C. § 102(b) as being anticipated by Levy et al. (U.S. Patent No. 5,780,060). The Office Action states that Levy discloses a dry aqueous-alcoholic blueberry extract which contains anthocyanosides in an amount corresponding to 15% of anthocyanidins. This rejection is respectfully traversed.

The CAFC has stated that anticipation requires the presence in a single prior art reference of the disclosure of each and every element of the claimed invention, arranged as in the claim. *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458 (Fed. Cir. 1984); *Altco Standard Corporation v. Tennessee Valley Authority*, 1 USPQ 1337, 1341 (Fed. Cir. 1986); 774 F.2d 1082 (Fed. Cir. 1985).

Claims 63 and 64 have been cancelled herein. With respect to claims 61-62, it is asserted that Levy does not teach every element of claims 61-62 as amended herein, and therefore cannot anticipate these claims.

As a first matter, it is asserted that while Example 17 of Levy states that a blueberry extract was utilized, the material used by Levy was in fact a bilberry extract based on the evidence presented below. Accordingly, since Levy essentially discloses a bilberry extract containing 15% anthocyanidins, Levy cannot anticipate claims 61-62, which are directed to a purified blueberry extract.

The fact that Levy used a bilberry extract can be demonstrated as follows. Levy states

that the extract was purchased from Indena. Enclosed with this response is a print out of Indena's product lists available on the World Wide Web at the following URL: www.indena.com. A review of these lists will show that the only berry extract sold by Indena is a bilberry (*Vaccinium myrtillus*) extract. Although bilberry (also known as "European blueberry") is sometimes simply called "blueberry" in some European languages (see printout obtained on the World Wide Web at the following URL: www.botanicalpathways.com), bilberry and blueberry (*Vaccinium spp.*) are in fact two distinct species (see printouts obtained on the World Wide Web at the following URL: www.hollandandbarrett.com). Based on the above information, it is asserted that the extract used in the Levy Example 17 was a bilberry extract, not a blueberry extract. Accordingly, Levy does not anticipate claims 61-62, and it is respectfully requested that the Section 102(b) rejection over Levy be withdrawn.

It is further asserted that Levy does not anticipate claims 65-66. Claim 65 is directed to a purified bilberry extract prepared by the method of claim 1 having an HPLC chromatogram as shown in Figure 3 or Figure 4. However, Levy does not provide an HPLC chromatogram of the Indena extract starting material. In addition, since Levy does not teach or even suggest using a brominated polystyrene resin to purify the extract as required in claim 1, Levy could not provide a composition having an HPLC chromatogram as shown in Figures 3 or Figure 4. Accordingly, Levy does not teach every element of claims 65, and therefore cannot anticipate claim 65. Since claim 66 depends from claim 65, it therefore includes the patentable subject material and likewise is not anticipated by Levy.

It is further asserted that new claims 72 and 73 are novel and nonobvious in view of Levy. Claim 72 recites a purified bilberry extract comprising about 8% anthocyanins by weight of the extract. Since the Indena extract used by Levy contains 15% anthocyanins by weight, the Levy reference is outside the scope of claim 72 and therefore does not anticipate claim 72. Similarly, claim 73 recites a purified bilberry extract comprising about 43-55% anthocyanins by weight of the extract, and therefore is also outside the scope of Levy.

Also submitted with this response is Chapter 3 from "The Flavonoids: Advances in Research" (J.B. Harborne and T.J. Mabry; Chapman and Hall, 1982). This chapter is being submitted to demonstrate that each anthocyanin-containing compound has a unique profile, i.e., the occurrence of anthocyanins in plants, fruits, etc. is different for each species (see Table 3.1). Accordingly, raw materials such as bilberry and blueberry contain different types and concentrations of anthocyanins, and therefore purified extracts obtained from bilberry and blueberry extracts will likewise contain different types and concentrations of the

anthocyanins.

2. Rejection of claims 53-54, 56-58, 60 and 65-68 over Gabetta et al.

Claims 53-54, 56-58, 60 and 65-68 are rejected under 35 U.S.C. § 102(b) as being anticipated by Gabetta et al. (U.S. 5,200,186). The Office Action states that Gabetta discloses a commercial *Vaccinium myrtillus* extract containing 35% of anthocyanosides. This rejection is respectfully traversed.

Claims 53, 54, 56-58, 60, 67, and 68 have been cancelled herein. With respect to claims 65-66, it is asserted that Gabetta does not teach every element of claims 65-66 and therefore cannot anticipate these claims. Independent claim 65 has been amended herein to recite a purified bilberry extract prepared according to the method of claim 1, wherein the enriched composition has an HPLC chromatogram as shown in Figure 3 or Figure 4. Gabetta does not provide HPLC chromatograms of his isolated compounds. Further, since Gabetta does not teach or even suggest using a brominated polystyrene resin to purify the extract as required in claim 1, Gabetta could not provide a composition having an HPLC chromatogram as shown in Figure 3 or Figure 4. Accordingly, Gabetta does not teach every element of independent claim 65 or claim 66 which depends therefrom, and therefore cannot anticipate claims 65-66. Withdrawal of this Section 102(b) rejection is respectfully requested.

It is further asserted that new claims 72 and 73 are novel and nonobvious in view of Gabetta. Claim 72 recites a purified bilberry extract comprising about 8% anthocyanins by weight of the extract, which is outside the scope of Gabetta. Similarly, claim 73 recites a purified bilberry extract comprising about 43-55% anthocyanins by weight of said extract, and therefore is also outside the scope of Gabetta.

F. Rejections under 35 U.S.C. §103(a) addressed

Claims 1-52 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Gabetta in view of Langston (U.S. Patent No. 4,500,556) and GB Patent No. 1,235,379 to S.O.R.I for the reasons discussed below. This rejection is respectfully traversed. The pending of this invention include at least one limitation that is not shown or made obvious by the cited references as discussed herein. Hence, a *prima facie* case of obviousness under 103(a) cannot be maintained.

As a first matter, the Examiner relies on the Langston and Gabatta references in part for teaching the use of bisulfite ions in isolating anthocyanins. Claims 29-60, 63, 64, 67, and 68 of the present invention, all of which relate to the two-column method involving the

addition of bisulfite ions during the process, have been cancelled herein. Therefore, the Examiner's rejection based on the fact that "Gabetta teaches adding a source of bisulfite ions" and Langston teaches "the use of bisulfite ions" is irrelevant in light of the pending as amended herein.

Next, the Examiner remarks that because Gabetta indicates "the broad use of the non-polar polystyrenic resin to which the brominated polystyrene resin may be belonged [*sic*]" and "there is little difference between their respective functionalities during the purification process" the brominated polystyrene resin "does not have any patentable weight over the prior art reference". These remarks demonstrate that the Examiner has not understood the distinguishing feature of this invention and therefore this rejection is improper. The method of this invention utilizes an unconventional resin in the purification step to isolate desired anthocyanins in a manner not previously described in the art. As discussed above, the surprising and unexpected discovery of this invention (and the crux of claim 1) is that since it was known in the art that the brominated polystyrene resin binds anthocyanins tighter than conventional polystyrene resins, it was not expected that a brominated polystyrene resin would be suitable for the purification of anthocyanins. However, it was surprisingly and unexpectedly discovered that the brominated polystyrene resin binds anthocyanins less tightly than non-brominated polystyrene resins, but still allowed for the separation of anthocyanins from undesired extraneous impurities that are more polar than the anthocyanins (see paragraph [0036]). Thus, the Examiner clearly has not considered the invention in its entirety. Further, the Examiner has not provided any evidence that suggests that a brominated polystyrene resin would be expected to be equivalent to a conventional polystyrene resin in its ability to isolate anthocyanins from an extract.

Given that none of the cited references disclose the use of a brominated polystyrene resin, let alone the use of such a resin to isolate desired anthocyanins from an extract, it can not be said that the cited references provide any guidance or suggestion whatsoever as to how to use the claimed method. On this basis alone the rejection should be withdrawn.

Next, the Examiner's remarks that the filtering step and the use of a filter aid do not have any patentable weight over the prior art references are immaterial to the pending claims. As stated above, the novelty of the claimed method lies not in the inclusion of a filtering step but rather on the novel use of a brominated polystyrene resin, which is neither taught nor suggested by the cited art. Thus, the fact that the cited references teach a filtering step does not render the present invention obvious.

In addition, the Examiner appears to be relying on the S.O.R.I reference primarily for

teaching the use of an anion exchange resin to enhance the purification of the isolated anthocyanins as recited in claim 24. The use of an anion exchange resin in dependent claim 24 is to achieve a higher purity of a unique composition isolated by the novel process of claim 1. Since the S.O.R.I reference does not teach or even suggest the use of a brominated polystyrene resin, the fact that it teaches the use of an anion exchange resin is irrelevant to the patentability of the present invention.


It is well known that to establish a *prima facie* case of obviousness, the prior art relied upon must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or to combine references (*In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988; *In re Fritch*, 972 F.2d 1260, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992). Second, the proposed modification of the prior art must have had a reasonable expectation of success (*Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1209, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art reference or combination of references must teach or suggest all the limitations of the claims. It is asserted that the Examiner has not met this burden and therefore has not established a *prima facie* case of obviousness. Therefore, in light of the foregoing remarks, it is asserted that claims 1-9, 11, 14-28, 61-62, 65-66, and 69 now pending are patentable over the cited references. Withdrawal of this rejection is respectfully requested.

CONCLUSIONS

All outstanding rejections having been addressed, claims 1-9, 11, 14-28, 61-62, 65-66, and 69-73 are believed to be in condition for allowance, and such action is respectfully requested. The fee required for a one month time extension is submitted herewith. Should any additional fees be due the Examiner is authorized to charge Deposit Account No. 50-1123. If any questions or issues remain to be resolved, the Examiner is requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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Dated


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